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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,637	03/24/2004	Jun Feng	DPP-IV-5004-C2	8940

32793 7590 08/20/2007
TAKEDA SAN DIEGO, INC.
10410 SCIENCE CENTER DRIVE
SAN DIEGO, CA 92121

EXAMINER

HABTE, KAHSAI

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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08/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/809,637

Applicant(s)

FENG ET AL.

Examiner

Kahsay Habte

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/8/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13, 15-25, 27-29, 31, 33-73 and 75-86 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 15-25, 33-73 and 75-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 27-29 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/5/2007 and 4/5/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 11-13, 15-25, 27-29, 31, 33-73 and 75-86 are pending in this application. Claims 11-12, 15-25, 33-73 and 75-86 are withdrawn from prosecution as being drawn to non-elected invention.

Applicants have to delete the withdrawn claims in response to this Office Action.

Response to Amendment

2. Applicant's amendment filed 08/08/2007 in response to the previous Office Action (3/15/2007) is acknowledged. Rejection of claims 13, 27-29 and 31 under 35 U.S.C. § 112, second paragraph (items 15a and 15d-15e) and the prior art rejections (9-14) have been obviated. The obviousness-type double patenting rejection (items 6-8) has been maintained. The second paragraph rejection (items 15b-15c) has been maintained. Upon further review of this case and applicant's amendment, it is deemed necessary to raise new issues that need further rejection.

Information Disclosure Statement

3. Applicant's Information Disclosure Statement, filed on 7/05/2007 and 4/05/2007 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 13, 27-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-15, 19-21, 23, 26-31, 33, 36, 42-43 and 55-61 of copending Application No. 10/809,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims 13, 27-29 and 31 and claims 1, 3-15, 19-21, 23, 26-31, 33, 36, 42-43 and 55-61 of copending Application No. 10/809,636.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments

Applicant's argument filed 8/08/2007 has been fully considered but it is not persuasive.

Applicants intend to address the rejection when one or both of the applications are otherwise in condition for allowance.

6. Claims 13, 27-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-17, 19-20, 22-25, 27, 38, 52-54, 56 and 111 of copending Application No. 10/809,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims 13, 27-29 and 31 and

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claims 8-17, 19-20, 22-25, 27, 38, 52-54, 56 and 111 of copending Application No. 10/809,635.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments

Applicant's argument filed 8/08/2007 has been fully considered but it is not persuasive.

Applicants intend to address the rejection when one or both of the applications are otherwise in condition for allowance.

7. Claims 13, 27-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-16, 19-20, 28-29, 32-38 and 48 of copending Application No. 10/809,638. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims 13, 27-29 and 31 and claims 1, 7-16, 19-20, 28-29, 32-38 and 48 of copending Application No. 10/809,638.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments

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Applicant's argument filed 8/08/2007 has been fully considered but it is not persuasive.

Applicants intend to address the rejection when one or both of the applications are otherwise in condition for allowance.

Claim Rejections - 35 USC § 102

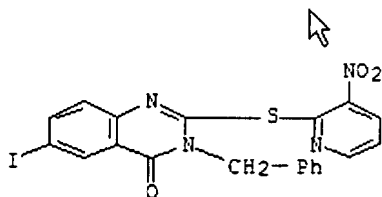
8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Abdel Hamid et al. *Scientia Pharmaceutica* (2001), 69(4), 351-366. Cited reference at page 353 teaches a compound of interests (compound 10) that is the same as applicants. Please see below for the chemical structure of compound 10.

RN 362662-14-4 HCAPLUS
CN 4(3H)-Quinazolinone, 6-iodo-2-[(3-nitro-2-pyridinyl)thio]-3-(phenylmethyl)-
(9CI) (CA INDEX NAME)

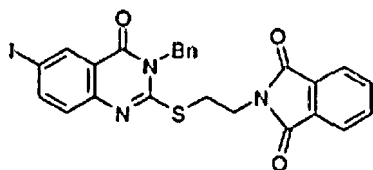


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Said compounds is the same as applicants when applicant's compound of Formula XXIX has the following substituents:

L = C-I; J = K= M= CH; R₁ = benzyl; U = S; and V = heteroaryl having a nitrogen atom.

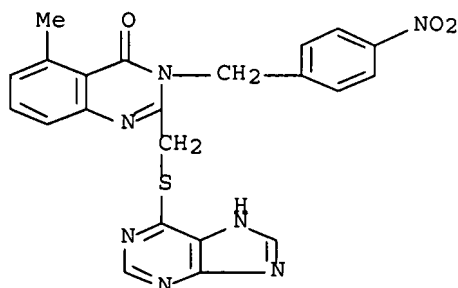
Note that since U can be substituted by alkyl, compound 25 (see page 355) is also the same as applicants.



25

9. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Sadhu et al. WO 01/081346 (equivalent to U.S. Pat. 6,518,277). Cited reference (U.S. Patent) at column 69 (lines 27-28, compound D 066) teaches the following compound of interest:

RN 371243-07-1 HCAPLUS
CN 4(3H)-Quinazolinone, 5-methyl-3-[(4-nitrophenyl)methyl]-2-[(1H-purin-6-ylthio)methyl]- (9CI) (CA INDEX NAME)

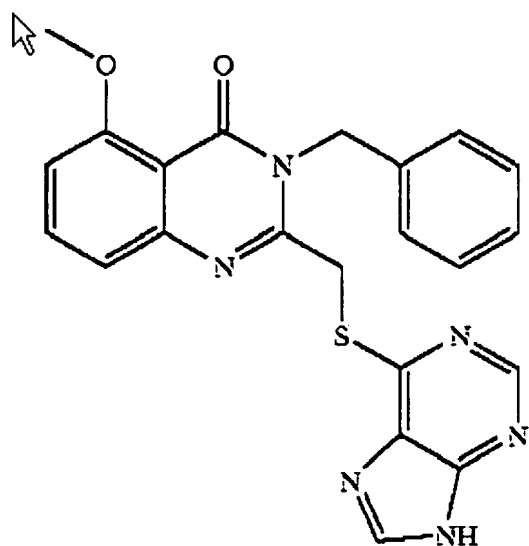
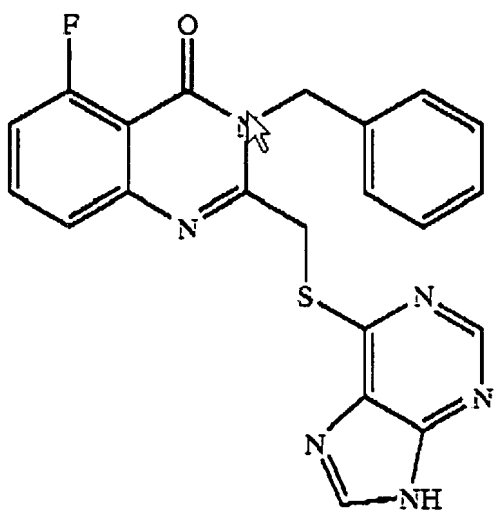


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that is the same as applicants when applicant's compound of Formula XXIX has the following substituents:

J = C-CH₃; K = L = M = CH; R₁ = benzyl substituted with nitro at para position; and R₂ = CH₂-S-purine.

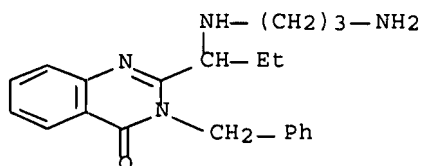
Cited reference at column 93 also teaches the following two compounds of interest that the following two compounds that are the same as applicants.



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10. Claims 13 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Finer et al. WO 01/030768 A1 (equivalent to U.S. Pat. 7,230,000). Cited reference teaches the following compound that is the same as applicants.

RN 336119-86-9 HCAPLUS
 CN 4 (3H)-Quinazolinone, 2-[1-[(3-aminopropyl)amino]propyl]-3-(phenylmethyl)-
 (9CI) (CA INDEX NAME)



Said compound is the same as applicants when applicant's compound Formula XXIX has the following substituents:

J = K = L = M = CH; R₁ = benzyl; and R₂ = CH(Ethyl)-NH-(CH₂)₃-NH₂ (i.e. U = C(R₉)(R₉) where R₉ = alkyl and the other R₉ = aminoalkyl and V = primary amine).

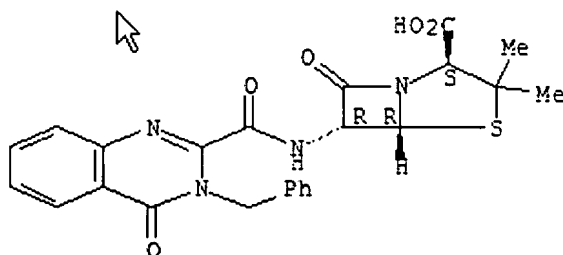
In addition, cited US patent teaches many quinazoline compounds at pages 76-86 that are the same as applicants.

11. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by GB 1377642. Cited reference at page 11 teaches the following compound that is the same as applicants.

RN 33015-32-6 HCAPLUS
 CN 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[[3,4-dihydro-4-oxo-3-(phenylmethyl)-2-quinazolinyl]carbonyl]amino]-3,3-dimethyl-7-oxo-, [2S-(2 α , 5 α , 6 β)]- (9CI) (CA INDEX NAME)

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Absolute stereochemistry.



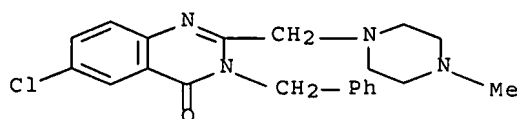
Said compound is the same as applicants when applicant's compound Formula XXIX has the following substituents:

J = K = L = M = CH; R₁ = benzyl; and R₂ = -CO-NH-heterocycloalkyl.

12. Claims 13 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 3,322,756. Cited reference at columns 7-8 teaches the following compound that is the same as applicants (see compound 44 or claim 11 of cited reference).

RN 2857-08-1 HCAPLUS

CN 4(3H)-Quinazolinone, 6-chloro-2-[(4-methyl-1-piperazinyl)methyl]-3-(phenylmethyl)- (9CI) (CA INDEX NAME)



Said compound is the same as applicants when applicant's compound Formula XXIX has the following substituents:

J = K = M = CH; L = C-Cl; R₁ = benzyl; and R₂ = -CH₂-(methylsubstituted)piperazinyl.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 27-29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 13 or elsewhere in the claims, the phrase "each R₁₂carbonyl group," is not clear. Carbonyl is a divalent substituent. How is carbonyl substituent substituted on the alkyl group? Does carbonyl group replace two hydrogen atoms in the alkyl group? For example -CH₂- becomes CO? Do applicants mean an oxo group substituted on alkyl? Note that carbonyl (C=O) is different from an oxo group (=O). If a carbonyl is substituted on alkyl, the molecule becomes charged.

Response to arguments

Applicant's argument filed 8/08/2007 has been fully considered but it is not persuasive.

Applicants did not address the "carbonyl" issue, instead deleted "oxo" from the definition of R₁₂ or other variables.

b. In claim 13 or elsewhere in the claims, the phrase "a heterocycloalkyl having a nitrogen atom and a heteroaryl having a nitrogen ring atom" is indefinite. What

is covered and what is not? What else is present in the ring except nitrogen atom? It is recommended that applicants recite specific rings to overcome this rejection.

Response to arguments

Applicant's argument filed 8/08/2007 has been fully considered but it is not persuasive.

Applicants amended the claims by replacing the term "comprising" with "having", but this would not overcome the rejection. Applicants are silent in responding to simple question raised in the previous Office Action. What other heteroatoms are present in the heteroaryl or heterocycloalkyl ring? Note that "having" is not different from the previous claim language (i.e. comprising).

c. In claim 13 (page 3) or elsewhere in the claims, the terms "alicyclic", "aromatic" and "aliphatic" in the definition of U is not clear. What do applicants mean by said terms? Aromatic what? How is aromatic used a substituent on linker U? Is this a typo? What is covered by aliphatic and what is not? It is recommended that applicants delete entire substituents for linker U.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571)-272-0667. The examiner can normally be reached on M-F (9.00- 5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kahsay Habte', with a stylized, cursive script.

Kahsay Habte
Primary Examiner
Art Unit 1624

August 16, 2007